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An intravascular catheter

This invention relates to an intravascular catheter useful for extracorporeal blood circulation through an artificial kidney, an artificial lung, or the like.

In a conventional blood dialyzing operation using an artificial kidney, a couple of needles are kept inserted respectively to each of the vein and artery of a patient for the suction and recovery of blood through the artificial kidney. In this case, the patient suffers from pain because two needles are inserted into his blood vessels. In addition, the life of the shunt serving to connect directly the artery and the vein tends to be shortened.

To overcome the above-noted drawbacks, a so-called "single needle system" has been proposed in which withdrawing from and returning to the body of the blood are effected by using a single needle. In this case, the opening-closing of a valve is performed electrically so as to enable the single needle to withdraw and return the blood alternatively. The alternate operation naturally leads to a longer dialyzing time than for the case of using two needles, because shortening of the dialyzing time will cause sharp and enlarged fluctuations in the internal pressure of the dialyzing circuit, giving bad influences to the patient. It should also be noted that the single needle system necessitates a particular machine for operating the circulation.

It is also known (see BE - A - 85 1 299) to provide a catheter in the form of a double-walled tube defining a central passageway and an annular passageway therearound. The catheter is provided with a branched passageway, which communicates with the annular passageway, and a needle is removably inserted through the central passageway and extends therebeyond. A plurality of bores are provided in the outer wall of the double-walled tube allowing blood to flow from the patient into the annular passageway and to the branched passageway. The blood is returned to the patient via the central passageway.

A disadvantage of such a catheter is that blood entering the annular passageway through the bores can stagnate in the pocket formed by the passage downstream of the bores, or bubbles can accumulate there. Up till now, the presence of such a pocket within the blood passageway of a catheter was regarded as unimportant. However, experiments have shown quite unexpectedly that such a pocket gives rise to pronounced blood coagulation. In fact, many examples of thrombi caused by blood coagulation have been recognized with such catheters. It is supposed that the blood coagulation is caused by the rapid change, disturbance and stagnation of the blood stream at the pocket portion. Further, the coagulation once formed is thought to grow gradually, leading to a thrombus.

Furthermore, if the catheter is flexible there is a tendancy for the outer wall of the double-walled tube to collapse around the bores as a result of the constricting force of the skin. This not only closes the annular passageway and restricts blood flow therethrough, but also causes considerable pain to the patient when the catheter is being operated.

The invention as claimed overcomes the above-mentioned disadvantages. Not only is the risk of blood stagnation and coagulation eliminated by providing the bores at the downstream end of the annular passageway, but the provision of a solid tapered tip tapering smoothly and uniformly from the outer tube reduces the risk of constriction of the annular passageway and reduces the risk of pain as the catheter is inserted in the patient.

Below, the invention is explained in greater detail by referring to the drawings illustrated preferred embodiments, and wherein:

Figure 1 is a longitudinal sectional view of an intravascular catheter according to one embodiment of this invention;

Figure 2 is a longitudinal sectional view of the hub included in the catheter of Figure 1;

Figure 3 is a view with parts broken away and in section of a vascular channel with catheter embodying the invention being inserted therein;

Figure 4 is a longitudinal sectional view showing a modification of a sealing member to be mounted to the base portion of the hub; and

Figure 5 is a longitudinal sectional view of an intravascular catheter according to another embodiment of this invention.

As shown in Figure 1, an intravascular catheter according to one embodiment of this invention comprises a hub 2, a double-walled tube 3 mounted to the tip portion of the hub 2 and having a tapered tip portion, and a needle 4 removably inserted into the double-walled tube 3. The hub 2, which is made of, for example, polycarbonate or polypropylene, is provided with an axial passageway 5 as shown in Figure 2. The base end portion of the hub is sealed with a sealing member 6 formed of, for example, synthetic rubber so as to close the axial passageway 5, with the tip end of the axial passageway left open. Further, the hub 2 is provided with first and second auxiliary passageways 7 and 8 branched from the axial passageway 5. In general, first and second auxiliary tubes 11 and 12 formed of a transparent flexible plastic material and having caps 9 and 10 (see Figure 1) removably mounted to the tips thereof are connected to the first and second auxiliary passageways 7 and 8, respectively.

The hub 2 may be formed by integral molding. Alternatively, it is possible to separate

the hub into two sections, one section comprising the first auxiliary passageway 7 and the other section including the second auxiliary passageway 8. Namely, these two sections are molded separately and joined to each other later. The separate molding method is preferred because the subsequent work of fixing an inner tube 13 to the hub can be facilitated.

A double-walled tube 3 consisting of the inner tube 13 and an outer tube is mounted to the forward end portion of the hub 2. Specifically, the base portion of the inner tube 13 is inserted into the axial passageway 5 of the hub to reach, for example, a stepped portion 14 provided between the first and second auxiliary blood passageway 7 and 8, and is bonded to the inner wall of the hub defining axial passageway 5 by using an adhesive or the like. Thus, the second auxiliary passageway 8 of the hub is allowed to communicate with a central passageway 15 formed in the inner tube 13. On the other hand, the base edge of the outer tube 16 is fixed to the forward end of the hub such that a flange 17 formed at the base edge of the outer tube is engaged with a stepped portion 18 of the hub, with reinforcing member 19 disposed to ensure stable engagement between the flange 17 and the stepped portion 18. Naturally, the particular construction mentioned permits a sufficiently strong fixing of the outer tube to the hub.

The outer tube 16 completely surrounds that portion of the inner tube 13 which extends from the forward end of the hub 2 so as to have an annular passageway 20 formed between the outer wall of the inner tube and the inner wall of the outer tube. As shown in the drawing, the annular passageway 20 communicates with the first auxiliary passageway 7 of the hub. In other words, the axial passageway 5 formed in the hub 2 is divided by the presence of the inner tube 13 into two independent passageways communicating respectively with the first and second auxiliary passageways 7 and 8.

The inner and outer tubes 13 and 16 are bonded to each other at the forward end portions by fusions or the like. Further, the double-walled tube 3 consisting of these tubes 13 and 16 has a tapered tip portion 21. When a needle 4 is inserted through the central passageway formed in the inner tube 13, the shape of beveled tip of the double-walled tube 3 nearly conforms with the shape of the tip of the needle 4, thereby substantially avoiding the formation of a stepped portion therebetween for ease in passage through the skin and vascular wall.

At least one bore, for example, a pair of mutually facing bores 23, 24, as shown in Figure 1, is formed in the tip portion of the outer tube 16 so as to enable the annular passageway to communicate with a blood vessel when the tip portion of the double-walled tube has been inserted into the blood vessel. It is essential that the bores 23, 24 communicate with the tip of the annular passageway 20 as shown in Figure 1. Otherwise, the blood introduced into the tip portion of the annular passageway would stagnate, leading to coagulation of the blood.

Incidentally, it is preferred to use a highly flexible plastic material such as TFE (tetrafluoroethylene) resin or FEP (fluorinated ethylene propylene) resin for forming each of the inner and outer tubes of the double-walled tube 3.

The needle 4 provided by, for example, a stainless steel tube is removably inserted through the elastic sealing member 6 into the central passageway formed in the inner tube. As shown in Figure 1, the tip of the needle is sharpened so as to facilitate insertion into a blood vessel, and the base of the needle is provided with a head 25. Further, a cap 27 equipped with a water-repelling filter 26 serving to withdraw the air from the needle is mounted to the head 25. When the needle 4, which is hollow, has been inserted into a blood vessel of the patient, the blood flows into the head 25 of the needle. Thus, it preferred to use a transparent material for forming each of the head 25 and the cap 27, so that blood flow introduced into the head can be observed through the transparent material, rendering it possible to confirm the insertion of the tip of the needle into a blood vessel.

Figure 3 illustrates the use of the intravascular catheter having the construction described above. Specifically, the sharpened tip of the needle 4 is inserted into a blood vessel 28 and, then, the needle 4 alone is withdrawn with the tip portions of the inner and outer tubes 13 and 16 left fully inserted within the blood vessel 28. As described above, the blood flows into the head 25 of the needle soon after the tip of the needle has penetrated the blood vessel 28. Since the head 25 is formed of a transparent material, the blood introduced therein is readily visible, rendering it possible to confirm that the tip of the needle has been properly inserted into the blood vessel 28.

It should be noted that the tapered tip portion of the double-walled tube 3 conforms well with the sharpened tip of the needle 4 as described previously. This construction is very effective for facilitating the insertion of the tip portion of the double-walled tube into the blood vessel 28. Specifically, the outer diameter of the tip of the double-walled tube is substantially equal to that of the tip of the needle such that the resistance to insertion is negligible, resulting in smooth inserting.

As soon as the needle 4 has been withdrawn, the puncture made by the needle insertion in the sealing member 6 closes under the elasticity of the sealing material, thereby preventing the blood from leaking to the outside through the sealing member. The sealing effect can be

enhanced if an auxiliary cap 29 is mounted to the base portion of the hub upon withdrawal of the needle 4.

After the intravascular catheter has been set as shown in Figure 3, the air within the catheter is vented. Namely, the caps 9 and 10 mounted to the first and second auxiliary tubes 11 and 12, which are connected to the first and second auxiliary passageways of the hub, are removed for the air withdrawing operation. Finally, a blood dialysis circuit 30 is connected to the auxiliary tubes 11 and 12 via connecting means. It is seen that the second auxiliary tube 12 constitutes a part of the passageway of blood flowing into the dialysis circuit 30. On the other hand, the first auxiliary tube 11 constitutes a part of the returning blood passageway. It is important to note that the bores 23, 24 provided at the tip of the outer tube 16 are suitably spaced from a port 31 leading to the center passageway formed in the inner tube 13. It follows that the blood returned to the blood vessel through the bores 23, 24 is prevented from again entering the dialysis circuit 30 through the port 31, as shown in Figure 3. Incidentially, Figure 3 shows that the double-walled tube inserted into the blood vessel 28 extends in the direction opposite to the flow direction of the blood; however, it is possible to reverse the inserting direction of the double-walled tube.

In the latter case, the blood circulation should also be reversed, i.e., the blood should be introduced into the catheter from the bores 23, 24, and returned to the blood vessel 28 through the port 31.

As described in detail, the intravascular catheter of this invention comprises a double-walled tube provided with two separate blood passageways through which the blood is introduced into an artificial kidney or the like and returned to the patient, respectively. It is important to note that the blood-treating circuit outside the body of the patient is rendered operable upon withdrawal of the needle inserted into a blood vessel of the patient. In other words, it suffices to insert the needle into a blood vessel only once for rendering the catheter of this invention operable. Naturally, trauma to the patient caused by the insertion of the needle can be markedly alleviated, and the life of the shunt can be increased, as compared with the conventional construction. Further, the intravascular catheter of this invention can be used in the blood dialysis system utilizing the conventional catheter comprising two needles.

The sealing member 6 mounted to the base end portion of the hub should naturally be formed of a highly flexible material. For enhancing the sealing effect, however, it is possible to employ various valve mechanisms. For example, Figure 4 shows a flexible sheet 32 mounted to the inner edge of the sealing member 6. Naturally, the sheet 32 acts as a valve so as to prevent the blood from leaking out through the sealing member 6.

Although the foregoing has been primarily described with respect to an intravascular catheter having a pair of auxiliary passages branched from the axial passage of the hub, it is also possible to omit the second auxiliary passageway 8 and to utilize the axial passage per se as the second auxiliary passage. Figure 5 shows an embodiment of such a construction wherein only the second auxiliary passageway 8 and the sealing member 6 are omitted. Accordingly, the intravascular catheter shown in Figure 5 comprises a hub 33 having an axial passage 34 opening at both ends, an auxiliary passageway 7 branched from the axial passageway 34, a flexible double-walled tube 3 having an inwardly tapered tip portion 21 and consisting of an inner tube 13 extending into the axial passageway 34 formed in the hub 33 and providing a central passageway 15 and an outer tube 16 disposed in coaxial relation to the inner tube 13, thereby forming an annular passageway 20 between the outer wall of the inner tube 13 and the inner wall of the outer tube 16, the base edge of the inner tube being secured at an intermediate inner wall of the axial passageway 34 between the auxiliary passageway 7 and the forward end of the axial passage 34, the base edge of the outer tube 16 being fixed to the forward end of the hub 33 so as to enable the annular passageway 20 to communicate the auxiliary passageway 7, and the central passageway 15 having an opening at the tapered tip 21 of the double-walled tube 3 and the forward end of the annular passageway 20 communicates with a pair of bores 23, 24 provided in the forward end portion of the outer tube 16, and a needle 4 removably inserted into the central passageway 15 formed in the inner tube 13 such that the tip of the needle 4 extends beyond the tapered tip 21 of the double-walled tube 3.

As described above, the catheter shown in Figure 5 makes use of part of axial passage 5 as the second auxiliary passageway 8. Accordingly, in the employment of this type of catheter, upon withdrawal of the needle 4 from a vascular channel, leaving the tip of the double-walled tube within the channel, one end of a blood circulating tube is connected to a recessed end portion 35 of the hub 2, thereby obtaining a blood circulation equivalent to that provided by the intravascular catheter shown in Figure 1. It is also possible to preliminarily provide the recessed end portion of the hub with an elastic reseal plug.

Claims

1. An intravascular catheter comprising a hub (2) having an axial passageway (5) open at the forward end thereof, an auxiliary passageway (7) branched from the axial passageway (5), a flexible double-walled tube (3) extending into the forward end of the hub (2) and having an inwardly-tapered tip portion (21) remote from

the hub, the double-walled tube (3) consisting of an inner tube (13) providing a central passageway (15) and an outer tube (16) arranged coaxially with respect to the inner tube (13) and forming an annular passageway (20) therearound, the annular passageway (20) communicating with the auxiliary passageway (7) and the central passageway (15) extending into the axial passageway (5) and being sealingly separate from the annular passageway (20) and the auxiliary passageway (7), there bing at least one bore (23, 24) in the outer tube (16) communicating with the annular passageway (20), and a needle (4) removably inserted into the central passageway (15) and having a needle tip extending beyond the tapered tip portion (21), characterised in that the tapered tip portion (21) is formed of the same material as the inner tube (13) and the outer tube (16), the central passageway (15) extends through the tapered tip portion (21) and terminates at the end thereof, the tapering tip portion (21) tapers smoothly and uniformly inwardly from the outer tube (16) and is of solid construction so as to facilitate insertion into a patient, the annular passageway (20) terminates at the beginning of the tapered tip portion (21) with the at least one bore (23, 24) arranged at the end of the annular passageway (20) adjacent the beginning of the tapered tip portion (21) thereby preventing blood stagnation at the end of the annular passageway (20).

2. The intravascular catheter according to claim 1, wherein a cap (27) having a water-repelling filter (26) for withdrawal of air from the needle is provided at the end of the needle remote from the tip.

3. The intravascular catheter according to claim 1 or 2, and further comprising a second auxiliary passageway (8) branched from the axial passageway (5) and communicating with the central passageway (15), a sealing member (6) being provided in the rearward end of the hub (2) and through which the needle (4) is removably inserted.

4. The intravascular catheter according to claim 3, wherein a flexible sheet (32) acting as a valve to prevent blood from leaking through the sealing member (6) is mounted at the inner end of the sealing member (6).

Revendications

1. Cathéter intravasculaire comprenant un corps (2) pourvu d'un passage axial (5) ouvert à son extrémité avant, un passage auxiliaire (7) monté en dérivation sur le passage axial (5), un tube souple (3) à double paroi faisant saillie à partir de l'extrémité avant du corps (2) et pourvu d'une pointe conique et effilée (21) à l'extrémité éloignée du corps, le tube à double paroi (3) consistant en un tube interne (13) déterminant un passage central (15) et un tube externe (16) monté coaxialement autour du tube interne (13) et constituant un passage annulaire (20), le passage annulaire (20) communiquant avec le passage auxiliaire (7) et le passage central (15) se prolongeant par le passage axial (5) et étant séparé de façon étanche du passage annulaire (20) et du passage auxiliaire (7), un alésage au moins (23, 24) étant pratiqué dans le tube externe (16) et communiquant avec le passage annulaire (20) et une aiguille (4) pourvue d'une pointe dépassant la pointe conique (21) étant insérée de façon amovible dans le passage central (15), caractérisé en ce que la pointe conique (21) est constituée dans la même matière que le tube interne (13) et le tube externe (16), en ce que le passage central (15) traverse la pointe conique (21) et se termine à son extrémité, en ce que la pointe conique (21) se présente sous une forme conique allant en s'amincissant de façon régulière et uniforme à partir du tube externe (16) et étant en une matière résistante pour faciliter l'insertion dans le patient, et en ce que le passage annulaire (20) se termine au commencement de la pointe conique (21), le ou les alésages (23, 24) étant pratiqués à l'extrémité du passage annulaire (20) dans une zone adjacente au début de la pointe conique (21), évitant ainsi le stagnation du sang à l'extrémité du passage annulaire (20).

2. Cathéter intravasculaire selon la revendication 1, caractérisé en ce qu'un bouchon (27) pourvu d'un filtre (26) hydrofuge est placé à l'extrémité de l'aiguille qui est éloignée de la pointe pour extraire l'air de l'aiguille.

3. Cathéter intravasculaire selon la revendication 1 ou 2, caractérisé en ce qu'il comprend, en outre, un second passage auxiliaire (8) monté en dérivation sur le passage axial (5) et communiquant avec le passage central (15), un organe interne d'étanchéité (6) par lequel est insérée de façon amovible l'aiguille (4) étant prévu à l'extrémité arrière du corps (2)

4. Cathéter intravasculaire selon la revendication 3, caractérisé en ce qu'une feuille souple (32) faisant fonction de valve pour empêcher le sang de fuir par l'organe d'étanchéité (6) est montée à l'extrémité interne de l'organe d'étanchéité (6).

Patentansprüche

1. Intravaskulärer Katheter, bestehend aus einer Nabe (2) mit einem am Vorderende offenen Axialdurchgang (5), einem vom Axialdurchgang (5) abzweigenden Nebendurchgang (7), einem sich in das Vorderende der Nabe (2) erstreckenden, flexiblen, doppelwandigen Rohr (3), das einen von der Nabe abgewandten, sich einwärts verjüngenden Spitzenabschnitt (21) aufweist und das aus einem einen zentralen Durchgang (15) bildenden Innenrohr (13) und einem koaxial zum Innenrohr (13) angeordneten und um letzteres herum einen ringförmigen Durchgang (20) bildenden Außenrohr (16) zusammengesetzt ist, wobei der ringförmige

Durchgang (20) mit dem Nebendurchgang (7) in Verbindung steht und sich der zentrale Durchgang (15) in den Axialdurchgang (5) erstreckt und unter Abdichtung vom ringförmigen Durchgang (20) und vom Nebendurchgang (7) getrennt ist, wobei das Außenrohr (16) mindestens eine Bohrung (23, 24) aufweist, die mit dem ringförmigen Durchgang (20) in Verbindung steht, und einer herausnehmbar in den zentralen Durchgang (15) eingesetzten Nadel bzw. Kanüle (4) mit einer über den verjüngten Spitzenabschnitt (21) hinausragenden Kanülenspitze, dadurch gekennzeichnet, daß der verjüngte Spitzenabschnitt (21) aus demselben Werkstoff wie Innenrohr (13) und Außenrohr (16) hergestellt ist, daß der zentrale Durchgang (15) durch den verjüngten Spitzenabschnitt (21) verläuft und an dessen Ende ausläuft, daß der verjüngte Spitzenabschnitt (21) stufenlos und gleichmäßig vom Außenrohr (16) einwärts konvergiert und zur Erleichterung der Einführung in einen Patienten massiv ausgebildet ist, daß der ringförmige Durchgang (20) am Anfangsteil des verjüngten Spitzenabschnitts (21) endet und daß die Bohrung(en) (23, 24) am Ende des ringförmigen Durchgangs (20) in der Nähe des Anfangsteils des verjüngten Spitzenabschnitts (21) angeordnet ist (sind) und dabei eine Blutstagnation am Ende des ringförmigen Durchgangs (20) verhindert (verhindern)

2. Intravaskulärer Katheter nach Anspruch 1, dadurch gekennzeichnet, daß eine Kappe (27) mit einem wasserabweisenden Filter (26) zum Abführen von Luft von der Nadel bzw. Kanüle an dem von der Kanülenspitze abgewandten Ende der Nadel bzw. Kanüle vorgesehen ist.

3. Intravaskulärer Katheder nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß ein zweiter Nebendruchgang (8) vom Axialdurchgang (5) abzweigt und mit dem zentralen Durchgang (15) in Verbindung steht und daß im hinteren Ende der Nabe (2) ein Dichtelement (6) vorgesehen ist, durch welches die Nadel bzw. Kanüle (4) herausnehmbar hindurchgeführt ist.

4. Intravaskulärer Katheter nach Anspruch 3, dadurch gekennzeichnet, daß eine als Ventil zur Verhinderung eines Blutaustritts über das Dichtelement (6) dienende elastische Lage bzw. Membran (32) am Innenende des Dichtelements (6) angebracht ist.

FIG. 1

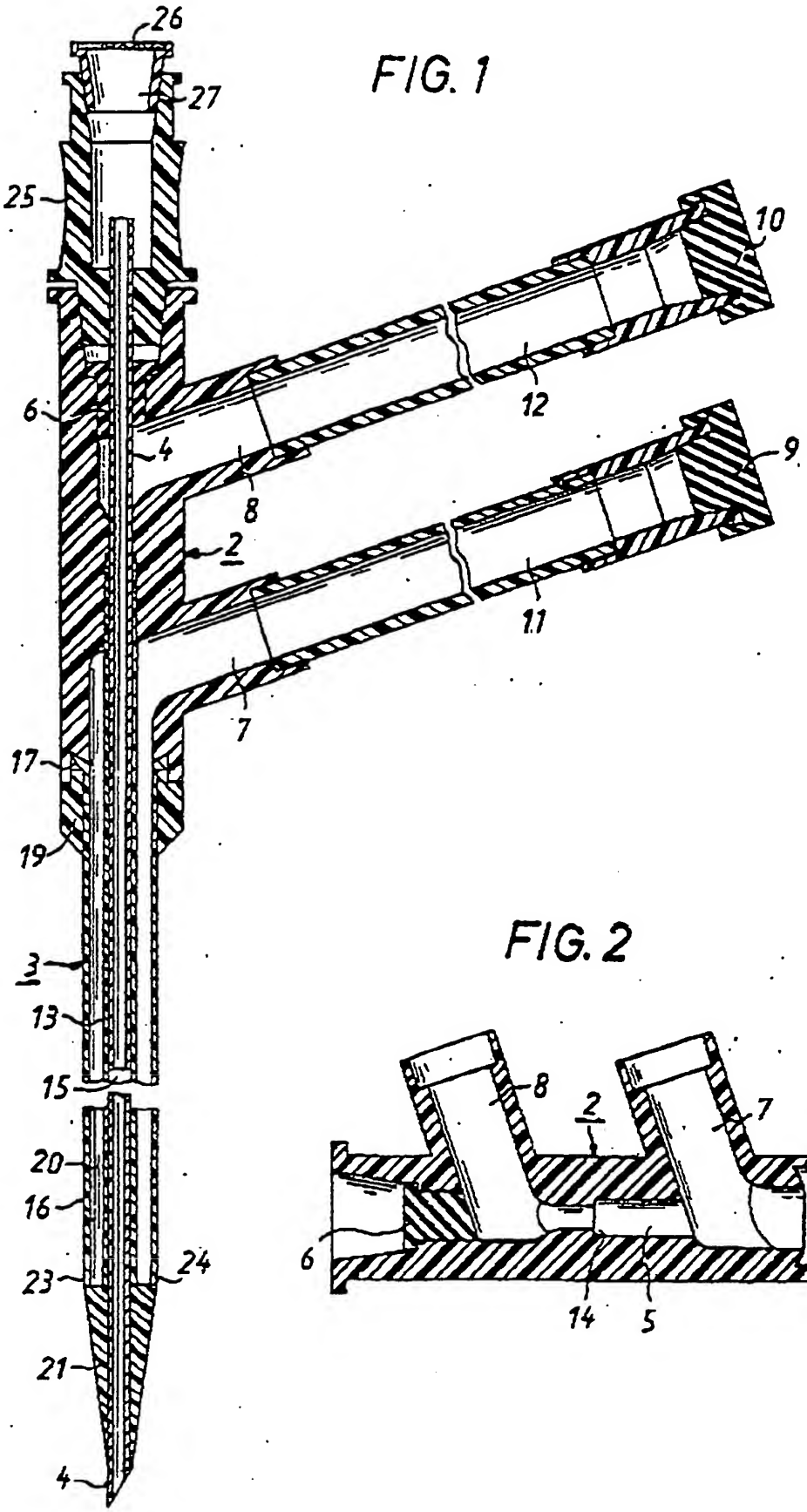


FIG. 2

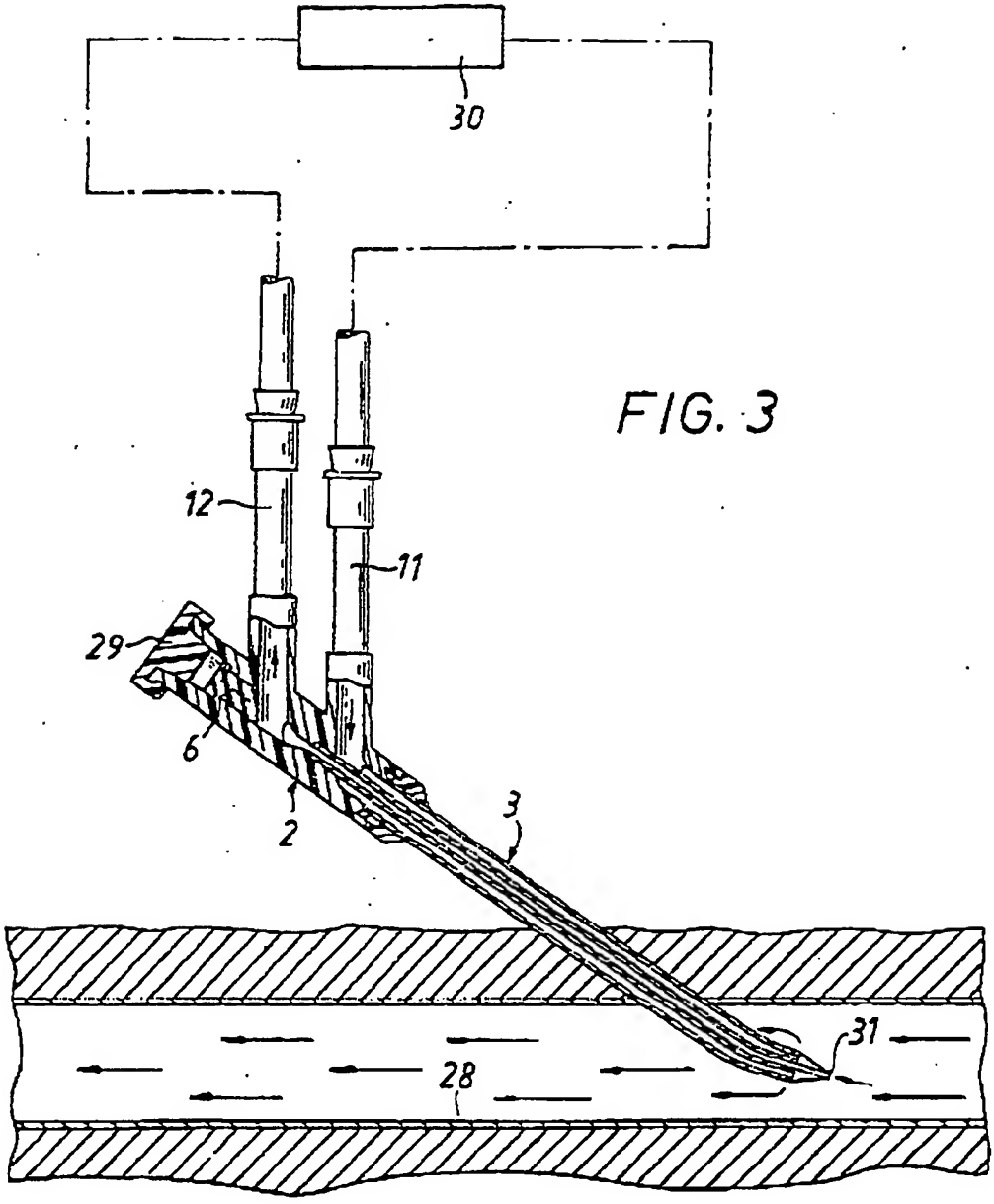
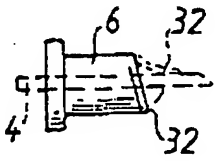


FIG. 3

FIG. 4



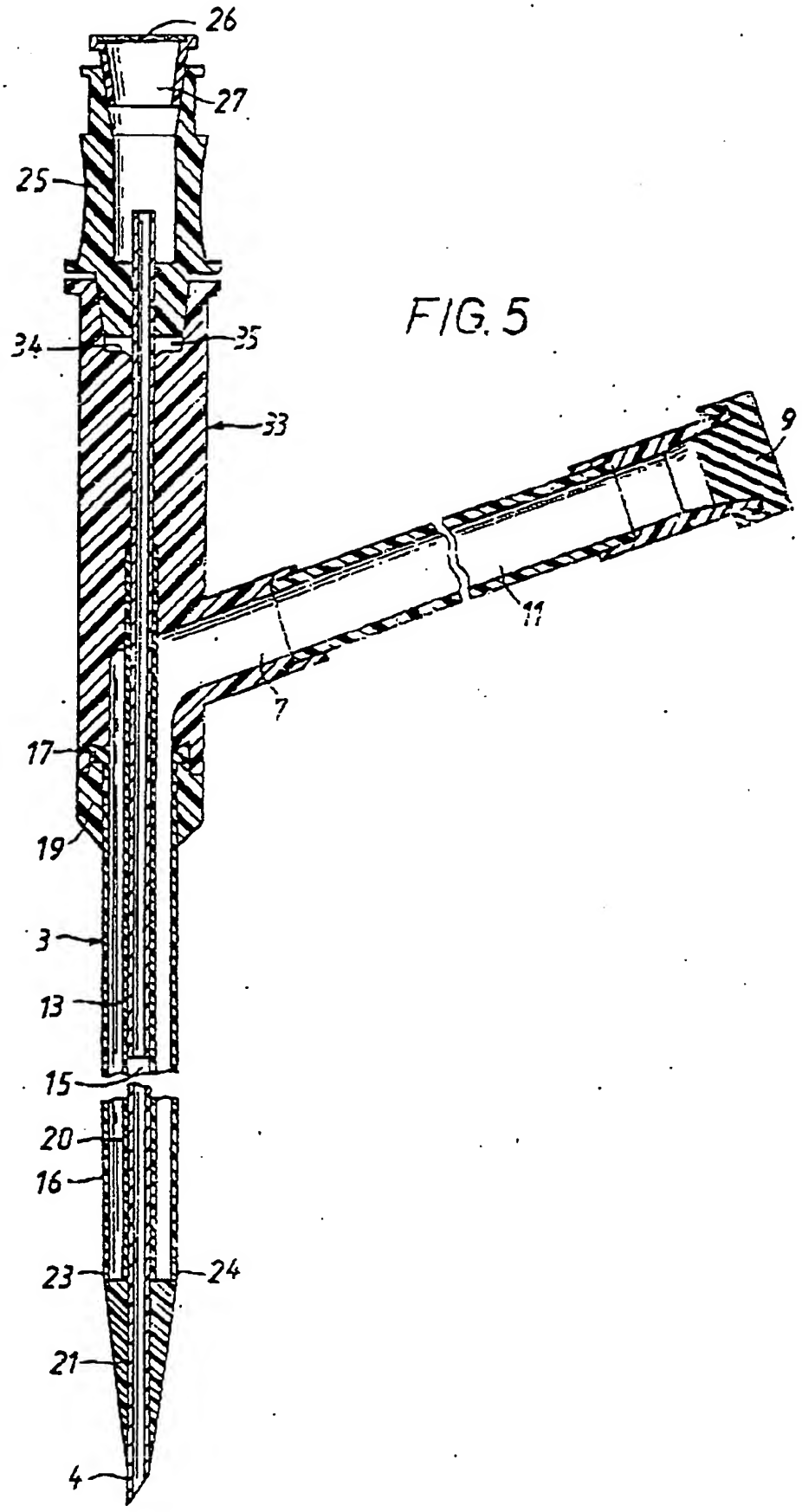


FIG. 5